

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0254]

Draft Guidance for Industry on Inhalation Drug Products Packaged in Semipermeable Container Closure Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Inhalation Drug Products Packaged in Semipermeable Container Closure Systems.” This draft guidance is intended to provide guidance for industry on inhalation drug products that are packaged in semipermeable primary container closure systems. This draft guidance also covers related chemistry, manufacturing, and controls (CMC) considerations. FDA is issuing this draft guidance to address public health concerns raised by the possible leaching and entry of chemical contaminants into inhalation drug products packaged in semipermeable primary container closure systems.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the **Federal Register***]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/>

ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Badrul Chowdhury or Guirag Poochikian, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Inhalation Drug Products Packaged in Semipermeable Container Closure Systems.” Inhalation drug products used in the treatment of patients with asthma or chronic obstructive pulmonary disease may be packaged in semipermeable primary container closure systems, such as low-density polyethylene. Over time, chemical impurities can accumulate in an inhalation drug product packaged in semipermeable primary container closure systems as a result of the degradation of formulation components, leaching from the container closure system, and/or entry from the local environment. Volatile chemical components from the local environment, including the secondary packaging, can react with the drug product formulation to form different impurities. The clinical consequences of chemical contamination of inhalation drug products are uncertain; however, given the known sensitivity of patients using these products to respiratory irritants and sensitizers, it is possible that these chemical contaminants may induce bronchospasm. Because bronchospasm is also the indication for which the inhalation drug product is used, it is difficult in the clinical setting to establish whether bronchospasm after the use of a drug product may be due to chemical contaminants or to a patient’s underlying disease. Since it is possible that chemical contaminants in the inhalation drug products used to treat critically ill patients could adversely affect such patients, FDA is issuing this draft guidance to provide recommendations for inhalation drug products packaged in semipermeable primary container closure systems. This draft guidance provides recommendations on: (1) Appropriate protective secondary packaging, (2) embossing and/

or debossing of the primary container in lieu of paper labels, and (3) general guidance on the number of unit-dose containers to be contained within each protective secondary package. These recommendations apply to drug products, both those in development and those already approved and marketed in the United States.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on inhalation drug products packaged in semipermeable container closure systems. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: July 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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